K081431

510(k) SUMMARY (per CFR21 807.92(c))

JUL 24 2008

GENERAL INFORMATION:

510k Owner's Name **Address**	Bovie Medical 7100 30th Avenue North St. Petersburg, Florida 33710-2902
Contact Person	Richard A. Kozloff Vice-President; Quality Assurance/Regulatory Affairs Telephone #: (727) 384-2323 FAX Number: (727) 347-9144
Date Prepared:	May 19, 2008

DEVICE DESCRIPTION:

Trade Name:	***Modular Ergonomic Instrument (MEG)***
Common Name:	Laparoscopic Electrodes
Classification Name:	Electrosurgical Cutting and Coagulation Devices and Accessories (21CFR 878.4400; Class II; Product Code: GEI)

510(k) SUMMARY (per CFR21 807.92(c))

DEVICE DESCRIPTION:

Predicate Devices:

Aaron Medical: Modular Monopolar Electrodes K062337

INTENDED USE:

Laparoscopic Electrodes are used to grasp, hold, coagulate, and cut tissue during laparoscopic surgical procedures.

DEVICE COMPONENTS AND OPERATION:

Laparoscopic electrodes are surgical instruments with single use or reusable interchangeable tip inserts designed to be introduced through a 5.5mm diameter (or larger) cannula, during laparoscopic surgical procedures. The devices can be used with electrosurgical generators. The interchange ability of the tip inserts allows for three main benefits:

- A removable insert allows for easier cleaning and disinfection of the instrument components,
- Versatility of the instrument is greatly increased as one handle can accept many tip configurations,
- Semi-disposability allows for multiple uses of one tip insert with cost effective replacement when worn or damaged.

Laparoscopic Electrodes consist of:

1) Tip Inserts (pre-sterilized single use and non-sterile reusable) that interchangeably fit into a reusable tube.
2) Cartridges (pre-sterilized single use) that fit directly into a reusable handle.
3) Reusable Tubes (non-sterile, reusable) that fit directly into a reusable handle and accommodates a variety of tip inserts.

Radiofrequency energy is delivered to the tip through the handle by using a powered lead from an electrosurgical generator to a connector port on the handle. The insulated handle (cleared in 510k # K062337) is the device that will be used by the physician or nurse to attach the tip and control the action of the tip via the grip. A rotary knob allows the tip to be positioned (rotated) while in the cannula.

510(k) SUMMARY (per CFR21 807.92(c))

These devices use technology that is substantially equivalent to Aaron Modular Monopolar Electrodes (K062337). Both consist of a series of electrodes that are used to cut and coagulate tissue through the utilization of high frequency radiofrequency energy.

Reusable Laparoscopic Electrodes are provided non-sterile and must be sterilized prior to use using steam sterilization.

Single use Laparoscopic Electrodes are provided sterilized using ethylene oxide gas.

Laparoscopic Electrodes conform to particular requirements of electrical safety standards ANSI/AAMI/ISO HF-18: 2001 Electrosurgical Devices and IEC 60601-2-2- 2006, Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment.

There are no significant differences in technology, performance, or intended use between Bovie Laparoscopic Electrodes and the given predicate devices. There are no new questions raised regarding safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 24 2008

Bovie Medical
% Mr. Richard A. Kozloff
VP, QA/RA
7100 30th Avenue North
St. Petersburg, Florida 33710-2902

Re: K081431
Trade/Device Name: MEG Laparoscopic Electrodes
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: May 19, 2008
Received: May 21, 2008

Dear Mr. Kozloff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081431

Device Name: MEG Laparoscopic Electrodes

Indications for Use:

MEG Laparoscopic Electrodes are used to grasp, hold, coagulate, and cut tissue during laparoscopic surgical procedures.

Prescription Use ✓ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081431